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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/938,048 | 08/23/2001 | C. Frank Bennett | ISPH-0567 | 1653 |

7590

03/09/2005

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| EXAMINER |
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MCGARRY, SEAN

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| ART UNIT | PAPER NUMBER |
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1635

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,048

Applicant(s)

BENNETT ET AL.

Examiner

Sean R. McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/03/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/03/04 has been entered.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-8, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to include the limitation "and wherein said one or more genes involved in the inflammatory response have an unknown identity". The inclusion of this language renders the claims indefinite. For example the genes are required by the claims to be "a cytokine or growth factor" (see claim 1, for example) and furthermore are required to be specified genes (see claim 4, for example). With the identity of the genes being required by the claims to be gene types ["a cytokine or growth factor"] or specified genes it is unclear what the metes and bounds of the newly added limitation is, for example.

Claim 6 recites, "wherein said compound is a cytokine or growth factor" there is no antecedent basis for the term "compound" in claim 1.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 6 and 10, and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al [US 6,080,580]. This rejection is maintained for the same reasons set forth in the Official Action mailed 6/27/03 and in view of the rejection under 35 U.S.C. 112, second paragraph, above.

The instantly claimed invention is drawn to a method for (1) identifying a gene involved in a response to a stimulus where the method comprises contacting cells with antisense from a library prior to the application of a stimulus, (2) where the response can be secretion of a compound (3) where the compound is a cytokine (4) the response is modulation of inflammation and where the response is inhibited.

Baker et al have disclosed the use of antisense from a library of antisense (see Table 1, Table 2 and Table 3, for example) targeted to TNF- α (a cytokine) which is involved in inflammation response (an inhibition of TNF- α correlates to an inhibition of a cellular inflammatory response (see column 1, for example). It has been disclosed in

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columns 19-20 a method wherein various antisense oligonucleotides (from a library) were added to different subpopulations of NeoHK cells (see also Table 3, for example). The cells were then treated with growth factors. After treatment the expression of TNF- α and the secretion of THF- α was measured. It is clear from Tables 2, 3, 5, 7 and 8 that the response to the stimulus expression of TNF- α mRNA and secretion of TNF- α secretion were variably stimulated and inhibited based on the conditions used and the particular antisense used, for example.

Claims 1, 2, 7, 8, 10, and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al [US 5,514,788]. This rejection is maintained for the reasons of record and in view of the rejection under 35 U.S.C. 112, second paragraph, above.

Bennett et al have disclosed the use of antisense targeted to various cell adhesion molecules, which are involved in inflammation. Inhibition of cell adhesion molecules inhibits inflammatory response of cells, for example (see columns 1-2, for example) Bennett et al have disclosed the inhibition of adhesion proteins such as ICAM VCAM and ELAM with antisense oligonucleotides from antisense libraries defined in Tables 1, 2, 3, and 4, for example. It has been disclosed in Example 1 VCAM, ICAM, and ELAM expression is measured after cells (subpopulations) were treated with antisense to various cell adhesion molecules prior to challenge of the cells to various cytokines. It can be seen in tables 3, 5, 4 and Example 6 the stimulation and inhibition of cell adhesion molecule expression in response to the application of various cytokines under various conditions, for example.

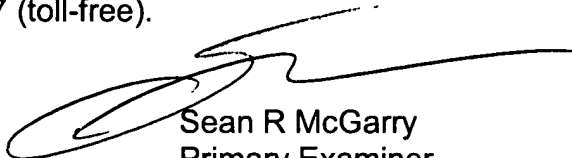
Applicant's arguments filed 12/03/04 have been fully considered but they are not persuasive. Applicant has argued that the new limitations added to the claims have rendered the claims novel over the prior art. Applicants arguments have been answered with the new rejection under 112 second paragraph above. Applicant arguments that the genes are "unknown" are not convincing in view of the lack of a clear context of the term "unknown" in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sean R McGarry', is written over the printed name.

Sean R McGarry
Primary Examiner
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SRM